

# **Proton Beam Therapy Treatment**

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Chairperson

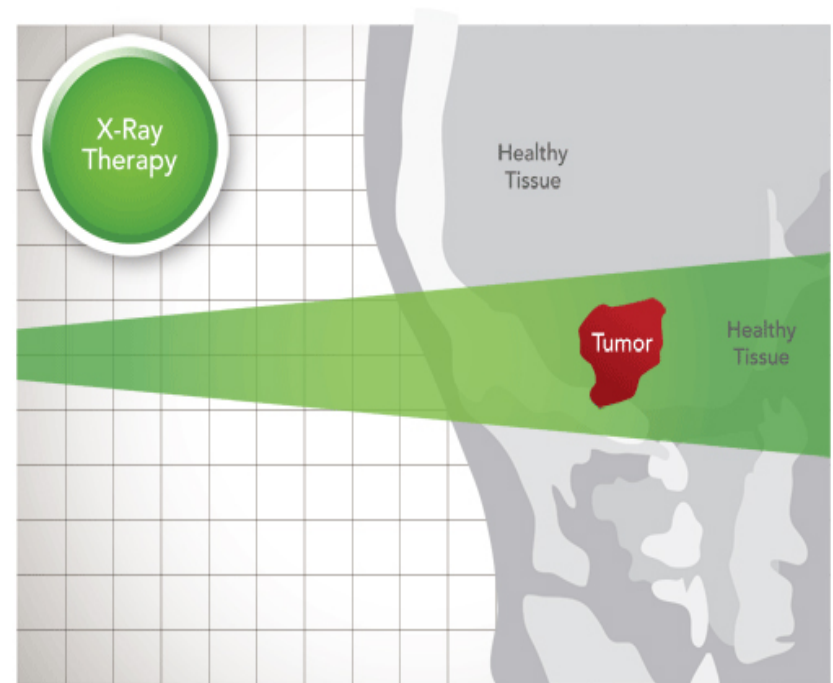
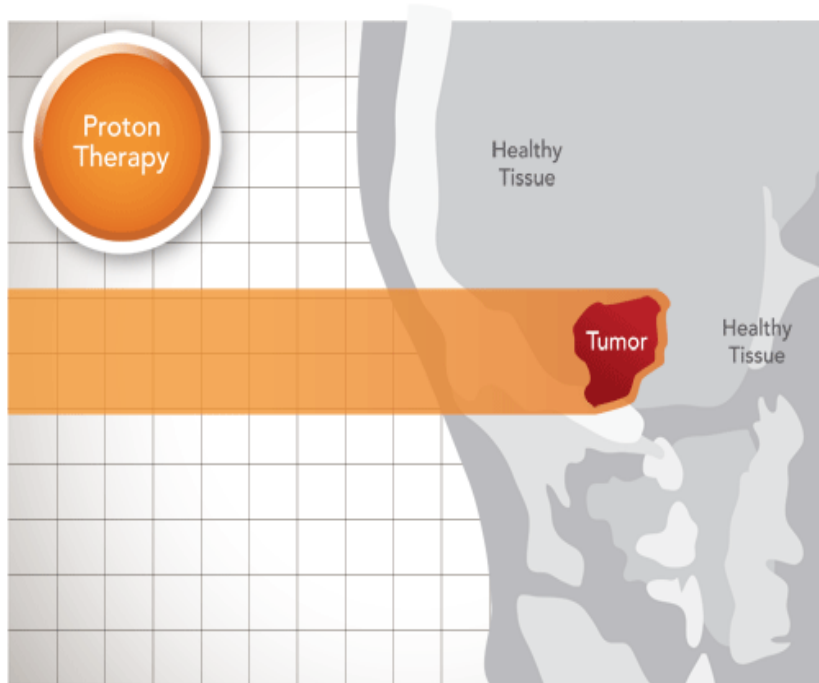
Workgroup

Proton Beam Therapy

# Principles of Radiation Therapy

- Ionizing radiation causes tumor cell death
- Take advantage of differences between tumor cells and normal cells
- Normal tissues can be harmed by excess radiation

# Proton vs X-ray (Photon) Therapy



- A lower dose of radiation is released at the surface, but a sharp burst of radiation is released as the proton beam reaches the tumor site.
- Proton radiation stops at the tumor, leaving the healthy cells beyond it unaffected.

- Radiation affects everything in its path so doctors often limit the dose to minimize damage to critical organs.
- X-rays continue to pass through the body after reaching the tumor, affecting the healthy cells beyond it.

# **Rationale Of Proton Beam Therapy (In Theory)**

- Lower or No Risk of Additional Cancers
- Higher dosage
- Retreatments

# ***How Many PBT Centers in Michigan?***

- Use of proton therapy is projected<sup>1</sup> to grow 19% annually over the next decade
- Preliminary demand projections<sup>2</sup> indicate Michigan population would utilize 2-3 PBT Centers for current indications,<sup>3</sup> once technology becomes available (37% of RT for these conditions)
- Utilization could expand to 6-7 Centers once technology becomes available and future indications develop<sup>4</sup>
- Even if only half this demand materializes over the next 5 years, Michigan population would utilize 2-3 Centers with current indications, 3-4 as new indications develop

Notes: (1) Source: SG2

(2) As noted above, medical need for PBT is still being evaluated.

(3) Prostate, brain & CNS, eye cancer, arteriovenous malformation)

(4) (breast, lung, colo-rectal, head & neck, and liver)

# Preliminary Market Analysis - Michigan

Indication	Cancer Incidence Rate (New Cases / 10,000 Pop)	Est. 2007 New Diagnoses	% Eligible for RT	# Patients Expected to Undergo RT	Potential Proton Therapy Penetration	Potential Proton Therapy Patients	Potential Demand for PBT Centers*
<i>Current</i>							2-3
Prostate	8.1	8,200	59%	4,838	51%	2,467	
Brain & CNS	0.7	740	78%	577	52%	300	
Arteriovenous Malformation	0.1	100	18%	18	60%	11	
Intraocular Melanoma	0.1	100	20%	20	100%	20	
			Subtotal:	5,453		2,798	
<i>Future</i>							3-4
Breast	5.9	5,900	70%	4,130	9%	372	
Lung	8.2	8,210	64%	5,254	37%	1,944	
Colorectal	5.5	5,570	38%	2,117	58%	1,228	
Head & Neck	1.5	1,500	77%	1,155	29%	335	
Liver	0.6	580	40%	232	20%	46	
			Subtotal:	12,888		3,925	6-7
			Total:	18,341		6,723	

\*Assumes 1000 patients, ~30K fractions per PBT center per year (Breakeven is currently 600 patients per year)

Sources: Morgan Stanley, U.S. Census Bureau; LEK Consultants; American Cancer Society; Michigan Dept of Community Health, BDC<sup>6</sup> Advisors

# What is the Evidence in Favor of Proton Therapy?

- Reviewed 36 published studies (only 2 phase III)
- Chordomas, ocular tumors, prostate, head and neck cancer

# Evidence Review

“...there are currently no studies demonstrating improved tumor control or survival in the treatment of localized prostate cancer with protons compared with best available photon RT. In addition, there is no clear evidence that high-dose proton boost is associated with less toxicity than the toxicity expected with photons.”

*Brada, et al JCO 2007*



# Cost

- An August 2007 article by Dr. Andre Konski looked at proton beam therapy versus IMRT for prostate cancer
  - Found proton beam therapy average cost was \$58,610
  - Found IMRT average cost was \$25,846<sup>1</sup>

1. Konski, A., Speier, et al. "Is Proton Beam Therapy Cost Effective in the Treatment of Adenocarcinoma of the Prostate?" Journal of Clinical Oncology. August 20, 2007 (25) 24: 3603-3608

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COMMENTS AND CONTROVERSIES

# Should Randomized Clinical Trials Be Required for Proton Radiotherapy?

*Michael Goitein, Department of Radiation Oncology, Harvard Medical School, Boston, MA*

*James D. Cox, Division of Radiation Oncology, The University of Texas M.D. Anderson Cancer Center, Houston, TX*

# Arguments for Protons

- **“Can anyone seriously believe that, if protons were cheaper than x-rays, there would be similar objections raised as to their immediate and widespread use?”**
- **“This seemingly rigorous academic discussion, in reality, is driven by the uncontested fact that protons are more expensive than x-rays.”**
- **“Although we can understand (though not necessarily agree with) the desire to rely on phase III trials to establish the advantage of a superior therapy, we find it totally unacceptable to insist on what we judge to be unethical phase III trials purely to establish the financial cost-effectiveness of an admittedly better technology.”**

**H. Goiten: Harvard Medical School/J. Cox: M.D. Anderson Cancer Center**

# Overview of

- Currently, five operating proton therapy centers across the country
  - Linda Loma University Medical Center: California
  - Massachusetts General Hospital: Massachusetts
  - MD Anderson: Texas
  - Midwest Proton Radiotherapy Institute: Indiana
  - University of Florida: Florida

- Pending Facilities
  - University of Pennsylvania: Pennsylvania
  - Oklahoma ProCure Treatment Center: Oklahoma
  - Seattle Cancer Care Alliance: Washington
  - Hampton University: Virginia
  - Northern Illinois University: Illinois
  - Central DuPage Hospital: Illinois
  - University of Oklahoma Cancer Institute: Oklahoma
  - Barnes-Jewish Hospital: Missouri

# Loma Linda University Medical Center

- First hospital based facility
- Opened in 1990
- Estimated cost of the facility \$60 million
- Given a federal grant of approximately \$20 million from the Department of Energy
- Privately financed the rest of the cost
- Medicare began covering treatment services right after the institute opened



# Massachusetts General Hospital

- Harvard University's Cyclotron Laboratory treated more than nine thousand patients from 1961 to its closing in 2002
- Proton treatment transferred to main campus of MGH
- Facility begins operation in late 2001/early 2002
- Costs of the facility \$46.1 million
- Jointly funded by MGH and the National Cancer Institute
- NCI provided \$26.1 million for the project
- MGH provided funding for the rest of the project which included philanthropic support from individuals and foundations

# Midwest Proton Radiotherapy Institute

- Treated first patient in 2004
- Built around an existing cyclotron owned by Indiana University
- Not attached to a hospital or university medical center; nearest hospital is 3 miles away
- Costs of the project \$20 million
- Indiana State Legislature provides \$10 million grant for the project
- Federal grants provided \$4.5 million

# MD Anderson Proton Therapy Center

- Began operation in 2006
- Total cost of project was \$125 million
- For-profit independent center, less than a mile from the nearest hospital
- MD Anderson provided the lease for the land valued at \$2.5 million
- Investment bank Sanders Morris Harris and healthcare facility developer the Styles Company raised the capital for the project
- Investors include pension funds, international health care companies, and private investors





# University of Florida

- Began operation in 2006
- Estimated cost between \$110-\$125 million
- Attached to University of Florida and Shands Medical Center
- State provided \$11 million grant
- Jacksonville Economic Development Commission provided \$80 million
- Private donations contributed a small amount



# University of Pennsylvania

- Estimated completion 2009
- Estimated cost \$140 million
- Will be part of the Perelman Center for Advanced Medicine, a large outpatient facility adjacent to the Hospital of the University of Pennsylvania
- Ralph Roberts and son Brian L. Roberts, founder and CEO of Comcast, provided \$15 million donation
- Department of Defense is providing substantial funding
- Penn Medicine and Children's Hospital will cover the remaining cost



# Oklahoma ProCure Treatment Center

- Estimated completion 2009
- Private practice proton treatment center, about 2 miles from the nearest hospital
- Estimated cost \$95 million
- Partnership of ProCure Proton Centers, Inc. and Radiation Oncology Associates and Radiation Medicine Associates
- Privately financed

# Northern Illinois University

- Expected completion 2010
- Estimated cost \$160 million
- Proposed location in West Chicago
- North of Fermi National Lab, little over 5 miles from the nearest hospital
- Currently has received \$7.3 million in federal funding
- Illinois Health Facilities Planning granted a certificate of exemption after NIU argued the facility is not a health-care facility under state law



# Central DuPage Hospital: Illinois

- Expected completion 2010
- Estimated cost \$125 million
- Construction and financing done through ProCure Treatment Centers, Inc.
- Tentatively planned to be attached to CDH
- Completely privately financed
- Proposed location in close vicinity to the NIU site
- Applying for a full certificate of need, Illinois Health Facilities Planning Board will consider the application at their April meeting

# Seattle Cancer Care Alliance

- Estimated date of completion 2010-2011
- Estimated cost \$100 million
- Will be part of Northwest Hospital's campus
- Received \$2.1 million in federal funds
- Equity investors
- SCCA will invest between \$10-\$20 million of its own money for the project



Fred Hutchinson Cancer Research Center  
University of Washington Academic Medical Center  
Children's Hospital & Regional Medical Center

# Hampton University

- Estimated completion 2010-2011
- Estimated cost \$225 million
- Will be the largest proton independent treatment facility in the world
- Will be located about 3 miles from the nearest hospital
- Received \$1 million from the state of Virginia
- Seeking federal funding
- Majority of cost will be privately financed

# Barnes-Jewish Hospital

- Approved by CON of Missouri
- Waiting for the approval of a smaller cyclotron unit developed by Still Rivers Systems
- Estimated cost \$20 million
- The miniature cyclotron has yet to be approved by the FDA
- Will be based within in a single hospital room



# University of Oklahoma

- Signed agreement to buy the small unit cyclotron from Still Rivers System
- Estimated cost \$20 million
- Proposed site for the cancer treatment center will be within blocks of Oklahoma Procure Treatment Center
- Will be part of the OU Cancer Institute, less than a mile from the main OU Medical Center Campus

# Conclusions

- Proton therapy has hypothetical advantages over photon therapy
- Presently, it would be used for prostate cancer
- Absolutely no evidence that proton therapy provides superior outcomes to photon therapy except in a few rare pediatric cancers
- Medicare pays more than twice as much for proton therapy as photon therapy

# Recommendations

- A consortium composed of Michigan hospitals should bring proton beam therapy to Michigan
- This consortium should have hospitals from at least four HSA
- All hospitals that have more than 30,000 ETV should be part of the consortium
  - Reason for 30,000 ETV is to ensure they have staff that have the expertise in radiation oncology
  - Ensure that hospitals are invited (an inclusive process)
  - Not too many hospitals that make the consortium unwieldy

# Recommendations (cont.)

- The consortium should attempt to enroll patients into clinical protocols so science can be advanced
- As more new expensive technology becomes available, a consortium can be a model for making new technology available in a cost effective manner

“Proton and other particle therapies need to be explored as potentially more effective and less toxic RT techniques. A passionate belief in the superiority of particle therapy and commercially driven acquisition and running of proton centers provide little confidence that appropriate information will be become available. Objective outcome data from prospective studies is only likely to come from fully supported academic activity away from commercial influence. An uncontrolled expansion of clinical units offering as yet unproven and expensive proton therapy is unlikely to advance the field of radiation oncology or be of benefit to cancer patients.”

***Brada, et al JCO 2007***